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Filed : January 20, 1999

epitopes are relevant to tolerization. Even if it is assumed that any conformational perturbation disrupts a conformational epitope, of which the Examiner provided no evidence, such conformational change will not alter linear epitopes. Moreover, tolerization with conformationally perturbed would also provide valuable information to a researcher interested in identifying those portions of an antibody fragment that do not contribute to conformational epitopes recognized as foreign antigens in a particular animal model. Such information would be useful in the development of a deantigenized antibody fragment in a particular animal model.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

(3) Claims 1, 5, 19, 21, 26, 19 and 31-36 were rejected under 35 U.S.C. § 112, second paragraph, as "being indefinite" in their recitation of the language "consisting essentially of." Since applicants found that the use of the term objected to is not necessary to describe the invention, claim 1 has been amended accordingly. It is emphasized, however, that the claim amendment was made without acquiescence in the present rejection or in the Examiner's position and arguments. Applicants specifically reserve the right to pursue claims similar to those as existed prior to the present amendment in one or more continuing applications.

As the claims no longer recite the allegedly indefinite term, the withdrawal of the present rejection would be in order.

(4) Claims 1, 5, 19, 21, 26, 28, 29, and 31-36 were rejected under 35 U.S.C. 102(e) "as being anticipated by U.S. Patent No. 6,133,426." Both U.S. Patent No. 6,133,426 (the '426 patent) and the present application claim priority to provisional application Serial No. 60/074,330 filed on January 22, 1998. To the extent that the '426 patent discloses subject matter claimed in the present application, that subject matter is entitled to the filing date of application Serial No. 60/074,330. Since the effective filing date of the cited disclosure in the '416 patent is the same as the priority date of the pending claims, the '426 patent is not a reference under 35 U.S.C. 102(e).

(5) Claims 1, 5, 19, 21, 26, 28, 29, and 31-36 were rejected under 35 U.S.C. 102(e) "as being anticipated by U.S. Patent No. 6,025,158." Both U.S. Patent No. 6,025,158 (the '158

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patent) and the present application claim priority to provisional application Serial No. 60/074,330 filed on January 22, 1998. To the extent that the '158 patent discloses subject matter claimed in the present application, that subject matter is entitled to the filing date of application Serial No. 60/074,330. Since the effective filing date of the cited disclosure in the '158 patent is the same as the priority date of the pending claims, the '158 patent is not a reference under 35 U.S.C. 102(e).

(6) Claims 1, 5, 19, 21, 26, 28, 29, and 31-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,133,426 (the '426 patent). The Examiner compares descriptions from the disclosure of the '426 patent with the claims of the present application. The judicially created doctrine of obviousness-type double patenting serves to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. Accordingly, a proper basis for this type of rejection exists only if any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent. In other words, the claims of the pending application are to be compared with the claims of the issued patent. The '426 patent claims anti-IL-8-antibodies and antibody fragments. The claims do not recite conjugates comprising an antibody or antibody fragment modified with a polyethylene glycol (PEG) molecule, and do not have any of the features recited in the claims pending in the present application. Accordingly, the Examiner is respectfully requested to withdraw this clearly erroneous rejection.

(7) Claims 1, 5, 19, 21, 26, 28, and 31-36 were rejected as being directed to an invention "not patentably distinct from claim [sic] of commonly assigned U.S. Patent No. 6,133,426 . . . for the reasons enunciated supra." The Examiner added that the '426 patent would form a basis for a rejection under 35 U.S.C. 102(f) or (g)/103(a), if the conflicting inventions were not commonly owned at the time the invention in this application was made.

It is hereby confirmed that "conflicting inventions" were commonly owned by Genentech, Inc. at the time the invention claimed in the present application was made. Accordingly, a proper 102(f) or (g) 103(a) rejection can not be raised.

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It is believed that the present application is in *prima facie* condition of allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Version with markings to show changes made

Claim 1 has been amended as follows:

1. (Twice amended) A conjugate [consisting essentially] of a single antibody fragment[, wherein the antibody fragment is] covalently attached to a single polyethylene glycol (PEG) molecule, wherein the antibody fragment is a Fab' comprising (1) a first chain that is either a light chain or a heavy chain and (2) a first opposite chain that is either a heavy chain opposite the first light chain or a light chain opposite the first heavy chain, wherein the PEG molecule is covalently attached to a first cysteine residue in the first chain that would ordinarily form a disulfide bridge with a second cysteine residue in the first opposite chain wherein the disulfide bridge is avoided by substitution of another amino acid residue for the second cysteine residue in the first opposite chain, wherein the apparent size of the conjugate is at least about 500 kD.

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